

**UNITED STATES DISTRICT COURT  
THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456  Civil Action No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO:  <i>State of Montana v. Abbott Labs Inc., et al.,</i> 02-CV-12084-PBS	Judge Patti B. Saris

**LOCAL RULE 56.1 STATEMENT OF  
UNDISPUTED FACTS IN SUPPORT  
OF PFIZER'S AND PHARMACIA'S  
MOTION FOR SUMMARY JUDGMENT**

Pursuant to Local Rule 56.1, defendants Pfizer Inc. (“Pfizer”), and Pharmacia Corporation and Pharmacia & Upjohn (together, “Pharmacia”) submit this statement of the material facts of record as to which there is no genuine issue to be tried in support of their motion for summary judgment.

1. From at least 1988 to the present, Montana Medicaid has included “Direct Price” in its definition of Estimated Acquisition Cost (“EAC”). (MT 013526 - MT 013530) (Declaration of Scott A. Stempel in Support of Pfizer’s and Pharmacia’s Motion for Summary Judgment (“Stempel Decl.”) Exh. 1.)

2. Effective October 1, 1994, Montana defined EAC using the following methodology: “Drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 10%. The policy for the reimbursement of Direct Price (DP) drugs (the price charged by manufacturers to retailers) is the current direct price (the direct price in effect on the date of service for the claim.” (MT 023015) (Stempel Decl. Exh. 2.)

3. Effective October 1, 2000, Montana defined EAC using the following methodology: “The Direct Price (DP), the price charged by manufacturers to retailers, will be paid unless the DP is not available to providers in the state. If no DP is available, drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 10%. If the state agency determines that acquisition cost is lower than either the available DP or AWP less 10%, then the state agency may set an allowable acquisition cost based on data provided by the drug pricing file contractor.” (MT 005705) (Stempel Decl. Exh. 3.)

4. Effective October 1, 2002, Montana defined EAC using the following methodology: “The Direct Price (DP), the price charged by manufacturers to retailers, will be paid unless the DP is not available to providers in the state. If no DP is available, drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 15 percent. If the state agency determines that acquisition cost is lower than either the available DP or AWP less 15 percent, then the state agency may set an allowable acquisition cost based on data provided by the drug pricing file contractor.” (MT 024346 – MT 024348) (Stempel Decl. Exh. 4.)

5. Montana does not currently reimburse any manufacturer's drugs at Direct Price. (Peterson Tr. at 83-84) (Stempel Decl. Exh. 12.)

6. Montana Medicaid reimbursed 83.7% of claims for Pfizer labeler code 00049 submitted between January 1991 and June 2001 at Direct Price. (Declaration of Eric M. Gaier, Ph.D., Concerning Direct Price Reimbursements for Pfizer Inc. and Pharmacia Corp. Drugs (hereinafter "Gaier Direct Price Decl.") at ¶ 4.)

7. Montana Medicaid reimbursed 95.8% of claims for Pfizer labeler code 00069 submitted between September 1995 and June 2001 at Direct Price. (Gaier Direct Price Decl. at ¶ 4.)

8. Montana Medicaid reimbursed 91.1% of claims for Upjohn labeler code 00009 submitted between January 1991 and June 1999 at Direct Price. (Gaier Direct Price Decl. at ¶ 4.)

9. Montana Medicaid reimbursed 51% of claims for Parke-Davis labeler code 00071 submitted between January 1991 and June 1992 at Direct Price. (Gaier Direct Price Decl. at ¶ 4.)

10. Exhibit A to Montana's Second Amended Complaint ("MT SAC") lists the following 21 Pfizer drugs: Accupril, Accuretic, Cardura, Celontin, Dilantin, Dilantin-125, Estrostep, FemHRT, Lipitor, Lopid, Minizide, Nardil, Neurontin, Nitrostat, Renese, Rescriptor, Viracept, Zarontin, Zithromax, Zolof, and Zyretc. (MT SAC, Exhibit A.)

11. Of those 21 drugs, all but Rescriptor and Viracept were reimbursed by Montana Medicaid at Direct Price during the time period at issue in this litigation. (Gaier Direct Price Decl. ¶ 6 n.5.)

12. Exhibit A to Montana's Second Amended Complaint lists the following 16 Pharmacia drugs: Adriamycin PFS, Adriamycin RDF, Adrucil, Amphocin, Amphoterecin B, Bleomycin Sulfate, Celebrex, Cleocin-T, Cytarabine, Depo-Testosterone, Etoposide, Neosar, Solu-Cortef, Solu-Medrol, Toposar, and Vincasar. (MT SAC, Exhibit A.)

13. Of those 16 drugs, five — Cleocin-T, Cytarabine, Depo-Testosterone, Solu-Cortef, and Solu-Medrol — were reimbursed by Montana Medicaid at Direct Price during the time period at issue in this litigation. (Gaier Direct Price Decl., Table 7.)

14. For 191,927 of 192,073 (99.9%) claims reimbursed at Direct Price, the Direct Price payments were lower than the published AWP less 10%. (Gaier Direct Price Decl. ¶ 5.)

15. Montana Medicaid received complaints from pharmacists that they were being insufficiently reimbursed when payments to them were made at Direct Price. (MT 013536) (Stempel Decl. Exh. 5); (Deposition of Dorothy Poulsen, 2/22/2006 (“Poulsen Tr.”) at 184-85) (Stempel Decl. Exh. 13.)

16. In 1998, Montana undertook a survey of pharmacies to determine how pharmacies were acquiring their drugs. (MT 005413 – MT 005415) (Stempel Decl. Exh. 6.)

17. That survey reflected that Montana pharmacists were acquiring Pfizer and Upjohn drugs through wholesalers and buying groups, rather than purchasing them directly from the manufacturers. (*Id.*)

18. In her February 22, 2006 deposition, Dorothy Poulsen, Montana’s Pharmacy Program Officer in 1998, was asked the following question and stated the following answer:

Q: Do you know whether the survey also looked at whether Montana pharmacies could acquire any drugs at published direct prices?

A: That was the issue, I believe, is that pharmacies in Montana had a great difficulty acquiring drugs at that price. And – and this is speculation on my part. It could be that our system was set up. Our reimbursement system, the PBM system was set up to take the lower of direct price or AWP minus 10%. And so for those labels that’s what I’m guessing. For those labels that were at direct price, they were paying at the direct price but our pharmacies were unable to get the drugs at that cost.

(Poulsen Tr. at 182-83) (Stempel Decl. Exh.13.)

19. In her deposition, Ms. Poulsen stated, “That based on the survey, they were asking – pharmacists were asking that we do away with direct price because they weren’t getting paid what they were having to pay. So they wanted to use AWP minus 10% for everything.” (Poulsen Tr. at 185) (Stempel Decl. Exh. 13.)

20. In a letter dated April 15, 1999 from Dorothy Poulsen to Jim Smith of the Montana State Pharmaceutical Association, Ms. Poulsen proposed the elimination of Direct Price reimbursement by Montana Medicaid. (MT 005370 – MT 005371) (Stempel Decl. Exh. 7.)

21. In her April 15, 1999 letter, Ms. Poulsen wrote that the Pharmacy Coordinating Committee “asked that Medicaid consider changing its reimbursement methodology for those labelers that currently pay at the direct price to average wholesale price less 10%.” (*Id.*)

22. Ms. Poulsen wrote that, because the legislature authorized a provider increase, “We now have an opportunity to implement a change in the direct price methodology.” (*Id.*)

23. Ms. Poulsen analyzed the program cost of changing from direct price reimbursement to average wholesale price less 10%, and found that “removing all the labels from direct price would result in an increased cost of approximately \$335,868 per year.” (*Id.*)

24. Because the legislature’s increase was for only \$148,208, Ms. Poulsen proposed that Montana Medicaid “phase in elimination of direct price reimbursement by removing labels 00005, 00008, 00009, 00662 and 00663 from this methodology for the 2000-2001 biennium. The analysis shows that this will result in approximately \$193,854 greater cost to the Medicaid pharmacy program. If the legislature authorizes another provider increase next biennium, we would continue to eliminate the labels subject to direct price.” (*Id.*)

25. Ms. Poulsen’s analysis of the cost to Montana Medicaid of changing from direct price reimbursement to average wholesale price is reflected in several handwritten and computer-generated documents. (MT 005372 – MT 005410) (Stempel Decl. Exh. 8); (Poulsen Tr. at 185) (Stempel Decl. Exh. 13.)

26. On May 27, 1999, Jim Smith replied to Ms. Poulsen after he had presented her proposal to the full membership of the Montana State Pharmaceutical Association at its annual convention, and wrote that, “you can be assured that the leadership of the Association, and the most active, involved members are quite enthused over this proposal.” (MT 005368 – MT 005369) (Stempel Decl. Exh. 9.)

27. Ms. Poulsen's understanding of this letter was that "Because the pharmacies were unable to acquire drugs at the direct price, which so far as I know, was less than AWP minus 10%. Having that pricing mechanism removed means they would be reimbursed at the AWP minus 10% charge or the usual and customary charge, whichever was less. And – and so they would either be able to meet their costs or they would make more money." (Poulsen Tr. at 189-90) (Stempel Decl. Exh. 13.)

28. In 2002, in response to public comments in opposition to the proposed change in reimbursement from AWP-10% to AWP-15%, Montana decided to increase the dispensing fee from \$4.20 to \$4.70, eliminate the use of Medicaid AWP prices, and wholly eliminate the use of Direct Price reimbursement. (MT 013531 – MT 013539) (Stempel Decl. Exh. 5.)

29. Montana had initially proposed raising the dispensing fee from \$4.20 to \$4.35, but in response to public comments, decided to raise it to \$4.70. (*Id.*); *see also* (MT 013526 - MT 013530) (Stempel Decl. Exh. 1.)

30. In response to a public comment that "[s]ome pharmacies indicate that the reimbursement for certain drugs are actually lower than the acquisition cost, particularly products by Pfizer and Abbott" Montana Medicaid responded:

The Department understands that pharmacies have been reimbursed below their cost for a select number of drugs made by Pfizer and Abbott. The reason for the underpayment is because selected drugs have continued to be reimbursed at direct price, when in fact direct prices are not available for the majority of pharmacies in the state, that is, pharmaceutical companies are not selling these drugs to pharmacies in Montana at the direct price. ARM 27.86.1101(1)(b) currently provides that if the direct price is not available to providers in the state, the estimated acquisition cost (EAC), on which reimbursement may be based, will be the AWP minus the discount specified in the rule. Thus, at the present time the EAC used to calculate reimbursement should be based on the AWP rather than the direct price.

For that reason, the Department has eliminated direct pricing from the reimbursement methodology effective June 5, 2002. This change will enable pharmacies to be paid at the lower of the EAC, Federal Maximum Allowable Cost (FMAC), or their usual and

customary charge. Subsection (1)(a) of ARM 37.86.1101, which defines the EAC as the direct cost, is being left in the rule because the direct price may be available to pharmacies in the state at some time in the future. The Department regrets not being able to change the reimbursement methodology sooner and will allow providers who have been paid incorrectly in the past year to reverse and resubmit those claims which were previously subjected to direct pricing.

(MT 013536) (Stempel Decl. Exh. 5.)

31. In facsimiles dated May 21, 2002, from Shannon Marr, Montana Medicaid's Pharmacy Program Officer, to Corvallis Drug and A&C Drug in which she explained that Direct Pricing would be removed from Pfizer 00049, Pfizer 00069, Abbott 00074, Pfizer 00063 and Pfizer 00995 labels, Ms. Marr apologized for under-reimbursing pharmacists for their purchases of Pfizer and Abbott drugs, and also confirmed that providers would be able to resubmit claims from within the previous year. (MT 005358 – MT 005359) (Stempel Decl. Exh. 10); (MT 005361 – MT 005362) (Stempel Decl. Exh. 11.)

32. Montana Medicaid had the option of using Direct Price, rather than AWP, as a basis of reimbursement and, in fact, did so for certain manufacturers' drugs.

33. Montana Medicaid recognized that reimbursement at Direct Price resulted in lower payments to providers than using the AWP-10% methodology.

34. After the filing of this lawsuit, Montana Medicaid chose to increase reimbursements providers by using the AWP methodology to reimburse for drugs that had previously been reimbursed at Direct Price.

35. Plaintiff's expert, Dr. Raymond Hartman, included 150,067 claims in his AWP penalty calculations that were reimbursed at Direct Price. (Gaier Direct Price Decl. ¶ 6.)

36. On October 29, 2002, Pfizer and the State of Montana entered into a settlement agreement regarding allegedly improper unrestricted educational grants by Warner-Lambert to the Ochsner Health Plan in New Orleans, Louisiana in 1999. (Settlement Agreement) (Stempel Decl. Exh. 14.)

37. The Settlement Agreement did not constitute an admission by Warner-Lambert of any liability or wrongful conduct. (*Id.*)

Respectfully submitted,

Dated: February 8, 2007

/s/ Mark D. Smith

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 8th day of February, 2007, a true and accurate copy of the Local Rule 56.1 Statement of Undisputed Facts in Support of Pfizer's and Pharmacia's Motion for Summary Judgment was served upon all parties of record via the Lexis-Nexis Filing System:

DATED: February 8, 2007.

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/s/ Mark D. Smith